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EXAMINER

FLOOD, M

ART UNIT

PAPER NUMBER

1651

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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# Office Action Summary

Application No.  
**09/242,215**

Applicant(s)

**McAnalley et al..**

Examiner

**Michele Flood**

Group Art Unit

**1651**



☒ Responsive to communication(s) filed on Feb 8, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1 and 6-21 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1 and 6-21 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☒ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 and 8

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8-10 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A grammatically error appears in Claim 17, line 5. Applicant may overcome the rejection by placing the word and before the word "zinc".

There is an apparent misspelling of a word in Claim 17, line 3. Applicant may overcome the rejection by replacing "panthothenic" with pantothenic.

Claims 8 and 15 are made vague and indefinite by "a blend of ripened and freeze-dried and powdered raw fruits and vegetables" because the phrase is confusing. It is uncertain as to how a freeze-dried and/or powdered product can be "ripened". The lack of clarity makes the claims ambiguous.

Claim 10 is made vague and indefinite by the use of both "consisting" and "comprising" because the use of both terms makes the claim inconsistent. The lack of clarity makes the claim confusing.

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***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by JP 57007420 (N).

Applicant claims a dietary supplement for providing nutritional product saccharides in monomeric, oligomeric or polymeric and derivatized or underivatized form, which saccharides are essential components of glycoproteins in a mammal, said dietary supplement comprising a composition consisting of nutritionally effective amounts of : at least one saccharide selected from a first group of saccharides consisting of galactose, glucose, mannose, xylose and acetylated mannose; and at least one saccharide selected from a second group of saccharides consisting of N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, galacturonic acid, iduronic acid, and arabinogalactan.

JP 57007420 teaches a composition comprising a cell wall component of *Aspergillus* fungi as an active component. The composition comprises the saccharides glucose, mannose, galactose and N-acetylglucosamine. The reference anticipates the claimed subject matter.

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Claims 1 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Cayen et al. (D).

The invention of Claim 1 was described above. Applicant further claims a dietary supplement wherein at least one of the saccharides is provided in oligomeric or polymeric form as found in at least one of: gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, aloe vera extract, gum ghatti, stack, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, acetylated polymannose, maltose glucan, lentinan, mannan, levan, hemi-cellulose, inulin, fructan, and lactose. Applicant further claims a dietary supplement comprising a nutritionally effective amount of dioscorea complex.

Cayen teaches a composition useful for lowering blood cholesterol and/or triglycerides, which is administered to hyperlipoproteinemic patients alone or formulated with a pharmaceutically acceptable carrier. The dietary supplement may also be mixed with a beverage, for example water, milk or a fruit juice, or a food, for example, soups or a pulpy fruit. The composition taught by Cayen comprises a mixture of diosgenin (dioscorea complex), a 4-substituted phenoxyisobutyric acid, and other active ingredients such as starch, sugars, and lubricants. See Column 3, lines 26-67 and Column 4, lines 1-33, wherein Cayen teaches that the diosgenin-containing dietary supplement may comprise as an active ingredient pectin or other water soluble gums, for example, sodium alginate, alginic acid, acacia mucilage,

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carboxypolymethylene, sodium carboxymethyl cellulose, gar, bentonite, cetyl alcohol, gelatin, methyl cellulose, polyvinyl alcohol, polyvinylpyrrolidone, propylene glycol monostearate, sodium lauryl sulfate, sorbitan monooleate, stearyl alcohol, carrageenin, malt extract, oleyl alcohol, quillaja, and tragacanth mucilage. The reference anticipates the claimed subject matter.

Claims 1, 6, 8-10 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Graves et al. (A).

The invention of Claim 1 was described above. Applicant further claims a dietary further comprising a nutritionally effective amount of a blend consisting of ripened and freeze-dried and powdered raw fruits and vegetables of broccoli, brussel sprouts, cabbage, carrot, cauliflower, garlic, kale, onion, papaya, pineapple, tomato and turnip. Applicant further claims a dietary supplement further comprising a nutritionally effective amounts of xanthines and herbal body-toning agents. Applicant further claims a dietary composition, wherein the composition comprises at least two saccharides selected from the second group of saccharides; and, wherein the composition comprises at least three saccharides selected from the second group of saccharides.

Graves teaches a dietary supplement that is produced by a process for enhancing the natural hypocholesterolemic effect of edible pulp, which is achieved by increasing the natural bile binding capacity of the fiber. The resultant modified pulp may be milled to form a flour which may then be employed in addition to or as a partial substitute for any of the commonly employed farinaceous compounds wherever such farinaceous compounds are employed. Alternatively, the

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modified pulp material may be granulated for use as a table-top dietary supplement which can be sprinkled onto various foods at the point of consumption. Optionally, the granulated table-top product may be combined with various herbs and spices. In Column 6, lines 53, Graves teaches that the major constituents of typical dietary fiber include cellulose, hemicellulose, lignin, and pectin. Graves teaches that pectin comprises the saccharides galactose, arabinose, xylose, and fucose. Sources of dietary fiber are selected from raw fruits such as apples, oranges, and grapefruit; and, raw vegetables such as carrots, corn, peas, and sugar beets; and grasses such as sugar cane; and grains such as barley and rice. The reference anticipates the claimed subject matter.

Claims 1, 6-7 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 59112922 (O).

The invention of Claims 1 and 6 was described above. Applicant further claims a dietary supplement further comprising a nutritionally effective amount of dioscorea complex. Applicant further claims a dietary supplement, wherein said composition comprises at least four or at least five saccharides selected from the second group of saccharides.

JP 59112922 teaches a dietary composition which has a blood sugar lowering effect, wherein the oligo- or polysaccharides of the composition are digestible. The composition taught by JP 59112922 contains cellulose, methylcellulose, ethylcellulose, nitrocellulose, hydroxyethylstarch, carboxymethylstarch, mannan, pectin, pectic acid, aloe mucilage, chondroitin sulphuric acid, hyaluronic acid, heparin, laminarin, alginic acid, propylene glycol alginic acid ester,

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agar-agar, gum arabic, arabinogalactan, carrageenan, dammar gum, elemi gum, ghatti gum, guar gum, karaya gum, kauri gum, tragacanth gum, plantain seed gum, inulin, xylan, galactomannan, tamarind seed mucilage, quince seed mucilage, flax seed mucilage, okra mucilage, and *Dioscorea japonica* mucilage. Although the reference does not expressly teach that the composition comprises at least five of the claimed saccharides selected from the second group of claimed saccharides, the existence of N-acetylglucosamine from chitin, the existence of arabinose, galactose, glucuronic acid, and the existence of mannosyluronic acid and gulosyluronic acid from alginic acid are inherent to the composition taught by JP 59112922, as evidenced by the admitted prior art disclosed on page 11 in Table 3 of the instant application. The reference anticipates the claimed subject matter.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor



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and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 59112922 (O) or Cayen et al. (D) in view of Pegel et al. (A).

Applicant claims a dietary supplement comprising saccharides and dioscorea complex, and further comprising a nutritionally effective amount of beta sitosterol.

The teachings of JP 59112922 and Cayen are set forth above. Neither JP 59112922 nor Cayen teach a dietary composition further comprising beta sitosterol. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify either of the compositions taught by JP 59112922 or Cayen by further adding beta sitosterol to provide the claimed composition because Pegel teaches a medicament having activity as a prostaglandin synthetase, comprising sterol glycosides, a fatty acid ester thereof or a spiroketal steroid glucoside or fatty acid ester thereof in an amount sufficient. The composition taught by Pegel comprises a spiroketalglycoside which carry an aglycone moiety such as diosgenin. In Column 5, lines 1-38, Pegel teaches a process for the production of a sitosterol- $\beta$ -glucoside of diosgenin. One of ordinary skill in the art at the time the invention was made would have been motivated and one would have had a reasonable expectation of success to add beta sitosterol to the Dioscorea complex containing compositions taught by JP 59112922 and Cayen to provide the claimed dietary supplement because Pegel teaches that the compounds of his invention are suited for

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treatment of many disease conditions, as described in Column 4, lines 37-53. This rejection is based on the well established proposition of patent law that no patentable invention resides in combining old ingredients of known characteristics where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett et al.*, 1266 USPQ 186.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graves (A) and JP 59112922 (O) and Cayen et al. (D) in view of Bonte et al. (B), and further in view of Balch et al. (U).

Applicant claims a dietary supplement comprising saccharides, nutritionally effective amounts of dioscorea complex and a blend consisting of ripened and freeze-dried and powdered raw fruits and vegetables. Applicant further claims a dietary composition comprising a nutritionally effective amount of melatonin. Applicant further claims a dietary supplement, further comprising an effective amount of an saccharide bioabsorption aid, wherein the bioabsorption aid comprises soy lecithin. Applicant further claims a dietary supplement further comprising nutritionally effective amounts of a dioscorea complex and a blend consisting of ripened and freeze-dried and powdered raw fruits and vegetables. Applicant further claims a dietary supplement further comprising nutritionally effective amounts of non-toxic vitamins and minerals,

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wherein the vitamins comprises A, B1, B12, B2, B6, carotene, bioflavonoids, biotin, C, choline D, E, folic acid, inositol, K, niacinamide, para-aminobenzoic acid, and pantothenic acid; and the minerals comprise boron, calcium, copper, GTF chromium, iodine, iron, magnesium, manganese, molybdenum, potassium, selenium, silicon, vanadium, and zinc.

The teachings of Graves, JP 59112922 and Cayen are set forth above. None of the references teach a dietary supplement further comprising an effective amount of melatonin, an effective amount of a saccharide bioabsorption aid or effective amounts of nutritionally effective amounts of non-toxic vitamins and minerals. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further add to the combined compositions taught in the teachings of Graves, JP 59112922, and Cayen effective amounts of each of the disclosed ingredients to provide the claimed composition because Bonte teaches a cosmetic or pharmaceutical composition comprising oxyacanthine and a saponin for stimulating hair growth or retarding hair loss, or combating pruritus. The oxyacanthine, an antitumor drug, is extracted from a plant. In Column 3, lines 50-52, Bonte teaches that the saponin can be extracted from *Dioscorea*. Other ingredients further comprising the composition taught by Bonte include the trace elements zinc and selenium (Column 5, line 34), soya lecithin (Column 6, line 47), and beta-sitosterol (Column 6, line 54). At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to further add the disclosed ingredients to the combined teachings of the compositions taught in the inventions of Graves, JP 59112922 and Cayen to provide the claimed composition

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because Bonte teaches that his novel formulation for the combining of active substances enhances its therapeutic effects. See Column 1, lines 60-63.

It also would have been obvious to one of ordinary skill in the art at the time the invention was made to add each of the other disclosed ingredients in effective amounts in the making of the instantly disclosed dietary supplement because Balch teaches that melatonin, vitamins, and minerals are essential to life and the maintenance of health. In particular, Balch teaches melatonin, selenium, vitamin A, vitamin C, vitamin E, beta-carotene, and zinc as antioxidants which protect the body from the formation of free radicals that can cause damage to cell, impairing the immune system, and leading to infections and various degenerative diseases. Moreover, Balch describes the disclosed vitamins and minerals as phytochemicals, which are biologically active substances found in fruits, vegetables, grains and legumes that appear to reduce the risk of cancer, heart disease, diabetes and high blood pressure. Balch specifically points to broccoli, brussel sprouts, cauliflower, cabbage, tomatoes and soybeans, as sources of plant materials containing health-benefiting phytochemicals, minerals, vitamins, and other nutrients. Thus, the teachings of Balch would also have made it obvious to one of ordinary skill in the art at the time the invention was made to include the instantly claimed fresh fruits and vegetables in a freeze-dried or powdered blend, and one of ordinary skill would have been motivated and had a reasonable expectation of success to include such a blend in the making of a diet supplement because Balch clearly teaches the protective effects of each of the disclosed ingredients found in plant materials. One of ordinary skill in the art at the time the invention was made would have been motivated and one

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would have had a reasonable expectation of success to add each of the ingredients taught by Balch to the composition taught in the combined teachings of Graves and JP 59112922 in the making of the claimed composition because Balch teaches that each of the ingredients are often used in the making of multivitamin formulations and can be sold as single supplements. This rejection is based on the well established proposition of patent law that no patentable invention resides in combining old ingredients of known characteristics where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett et al.*, 1266 USPQ 186.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graves et al. (A) in view of McAnalley et al. (AD, US Patent 5,308,838).

Applicant claims a dietary supplement comprising saccharides, a nutritionally effective amount of a blend consisting of ripened and freeze-dried and powdered raw fruits and vegetables, and further comprising a nutritionally effective amounts of xanthines and herbal body toning agents.

Graves teaches a dietary supplement that is produced by a process for enhancing the natural hypocholesterolemic effect of edible pulp, which is achieved by increasing the natural bile binding capacity of the fiber. The resultant modified pulp may be milled to form a flour which

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may then be employed in addition to or as a partial substitute for any of the commonly employed farinaceous compounds wherever such farinaceous compounds are employed. Alternatively, the modified pulp material may be granulated for use as a table-top dietary supplement which can be sprinkled onto various foods at the point of consumption. Optionally, the granulated table-top product may be combined with various herbs and spices. In Column 6, lines 53, Graves teaches that the major constituents of typical dietary fiber include cellulose, hemicellulose, lignin, and pectin. Graves teaches that pectin comprises the saccharides galactose, arabinose, xylose, and fucose. Sources of dietary fiber are selected from raw fruits such as apples, oranges, and grapefruit; and, raw vegetables such as carrots, corn, peas, and sugar beets; and grasses such as sugar cane; and grains such as barley and rice.

Although Graves mentions that his dietary supplement can further comprise various herbs, Graves does not expressly teach which herb can further comprise the referenced composition. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further add to the composition taught by Graves an herbal body-toning agent in the making of the instantly claimed dietary supplement because McAnalley teaches a composition comprising acemannan derived from aloe. McAnalley teaches that the composition is effective in treating a number of disease conditions where the principal mechanism of resolution or cure system requires intervention by the patient's immune system. One of ordinary skill in the art at the time the invention was made would have been motivated and one would have had a reasonable expectation of success to modify the composition taught by Graves to make the claimed dietary

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supplement because McAnalley teaches that the composition is effective for treating cancer, viral diseases, respiratory and immune respiratory diseases, inflammations, infections, infestations by administering an effective amount of acetylated mannan derivative, such as acemannan derived from aloe. This rejection is based on the well established proposition of patent law that no patentable invention resides in combining old ingredients of known characteristics where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett et al.*, 1266 USPQ 186.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

mcf

January 26, 2001

  
**LEON B. LANKFORD, JR.**  
**PRIMARY EXAMINER**